

### **REMARKS/ARGUMENTS**

At the outset, the courtesies extended by the Examiner in granting the telephone interview of 24 October 2006 are appreciatively noted. During the telephone interview, the references cited by the Examiner in the 9 June 2006 final Office Action were discussed in light of the clarifying amendments proposed to the pending claims by the undersigned attorney, as set forth herein.

Agreement as to the claims having been reached during the telephone interview in light of the cited art of record, Claims 1, 8 and 9 are amended to further clarify their recitations, responsive to the 9 June 2006 final Office Action and the discussions had during the telephone interview.

In the final Office Action, the Examiner objected to the Specification due to the fact that the Abstract of the Disclosure exceeded 150 words in length. In response to this objection, that Abstract has been amended and no longer exceeds 150 words in length.

In the final office Action, the Examiner objected to Claim 1 due to informalities therein. In response to this objection, Claim 1 has been amended to correct the informalities found therein.

In the final Office Action, the Examiner rejected Claims 4 – 6 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner stated that the claims contained subject matter which was not described in the Specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In response to this rejection, Claims 4 – 6 have been canceled therefore obviating the Examiner's rejection.

In the final Office Action, the Examiner rejected Claims 1, 2, 7, 8 and 12 under 35 U.S.C. § 103(a) as being unpatentable over the Termanini reference. In this regard, the Examiner acknowledged that the Termanini reference failed to disclose various functional limitations but stated that the claims must be structurally distinguishable from the prior art.

Also in the Office Action, the Examiner rejected Claims 9 – 11 under 35 U.S.C. § 103(a) as being unpatentable over the Baskin reference in view of the Rosenberg reference. In this regard, the Examiner acknowledged that the Baskin reference failed to disclose a valve, however, cited the Rosenberg reference for disclosing a valve (48) and concluded that it would have been obvious to one of ordinary skill in the art to have accordingly modified Baskin's device.

As newly-amended independent Claims 1 and 8 each now more clearly recite, Applicant's self-retaining urinary drainage catheter system is one which includes among its combination of features "inherently resilient flexible tube slit portions devoid of separate spring members." As Applicant's claimed catheter is inherently resilient, such obviates the need for separate spring members, either plastic or metallic, which are dangerous features in a catheter capable of causing damage to the device itself and more importantly to a patient.

The full combination of these and other features now more clearly recited by Applicant's pending claims is nowhere disclosed nor suggested by the cited Termanini reference. As the Examiner readily acknowledged, the reference did not disclose various "functional" limitations. Moreover, the Termanini reference necessitates spring elements 24 embedded in the wings 22 of its catheter. The reference specifically states that the "spring elements 24 are disposed in wings 22 to assume an unstressed position when the wings are flush with the adjacent unslitted portions of the tubular member 12." Furthermore, the spring elements 24 "extend[s] substantially along the length [of the wings 22]." Functionally, when withdrawal of the Terminini catheter is desired, the flexible member is released whereupon the restoring force of the spring elements 24 returns the wings 22 to the flush position.

As Applicant's claimed catheter incorporates flexible tube slit portions that are "inherently resilient" and "devoid of separate spring members" such obviates the need for separate spring elements 24 as necessitated by the Terminini reference. Terminini discusses at length that the spring elements may be helical or of a leaf spring but that breakage of such springs "could cause severe damage to the bladder and urethra." The reference further states that wire springs comprise a still further alternative but possess the same disadvantages as leaf springs. The obvious damages of metal springs "possibly causing severe damage to the bladder and urethra," can be replaced by plastic spring elements, which the Terminini

reference states is “less advantageous”. The reference states specifically that “plastic springs are not preferred since they may take on a set with extended periods of deflection.”

The Terminini reference, knowing and discussing the inherent dangers and problems of spring elements, still utilizes such in its catheter. Whereas, Applicant’s claimed catheter obviates the need for such spring elements, a novel concept neither disclosed nor suggested by the Terminini reference.

As newly-amended independent Claim 9 more clearly recites, Applicant’s claimed catheter includes a flexible tube defining only one single lumen. A reversibly inflatable balloon is located “internal said single lumen” and positioned between the plurality of flexible tube slit portions and connected to an ejectable valve situated adjacent to the open distal end of the flexible tube.

The full combination of these and other features now more clearly recited by Applicant’s pending independent Claim 9 is nowhere disclosed by the cited Baskin and Rosenberg references. As the Examiner readily acknowledged, the primarily-cited Baskin reference nowhere discloses a valve member. As can be readily seen in the figures of the Baskin reference, the inflatable bag “encircles the tubular member rearward of the openings and is secured thereto.” (Column 1, lines 59 – 61) The Baskin catheter then uses a “means” within the outer confines of the tubular member for transmitting a fluid into the inflatable bag for the purpose of inflating the bag. The means is “independent of the central passage

and includes a second longitudinal passage in the wall of the tubular member that extends from the rear end of that wall to a point between the ends of the bag.” In order to prevent obstruction of the entrance openings 18, the Baskin reference has strut elements that are adapted, upon inflation of the bag, to extend over and in spaced relation to a corresponding entrance opening 18. The strut element extends between the forward end of the tubular member and the inflatable bag. Whereas, Applicant’s claimed catheter incorporates its inflatable bag within its only one single lumen with slits being transformed into openings upon inflation of its balloon, thus obviating the need for “strut elements.” The strut elements, when displaced upon inflation of the inflatable bag, can lead to irritation of the urinary bladder due to the volume of space that such occupies when inserted therein.

Furthermore, the Baskin reference necessitates multiple lumens, one for drainage purposes and another for inflation of the inflatable bag. Such is obviated by Applicant’s claimed catheter thereby forming a more streamlined device that is better adapted for and safer in draining the urinary bladder. It is of utmost importance to minimize elements with such types of catheters so that damage to the urinary bladder does not occur.

The secondarily-cited Rosenberg reference was relied upon for disclosing isolated features but fails to remedy the deficiencies of the primarily-cited Baskin reference.

It is respectfully submitted, therefore, that the cited Terminini, Baskin and Rosenberg references, even when considered together, fail to disclose or suggest the unique combination of elements now more clearly recited by Applicant's pending claims for the purposes and objectives disclosed in the subject Patent Application.

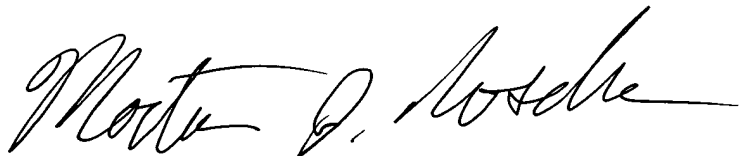
It is now believe that the subject Patent Application has been placed in condition for allowance, and such action is respectfully requested.

If there are any further charges associated with this filing, the Honorable Director for Patents and Trademarks is hereby authorized to charge Deposit Account 18-2011 for such charges.

Respectfully submitted,  
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